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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,571	11/28/2001	Richard A Dixon	NBLE:025US	8964

7590

07/29/2004

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,571	DIXON ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-10,36 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10,36 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 4, 5, 11-14 and 37-38 are cancelled. Claims 1-3, 6-10, 36 and 43-46 are pending and examined.

Rejection of Claims 44-46 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments.

Rejection of Claims 5, 12, 14, 38 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-10, 36 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The added claimed material which is not supported by the original disclosure is as follows: Newly amended Claims 1-3, 6-10, 36 and 43-46 recite "exhibiting hybridization with SEQ ID NO: 1 under conditions of 0.2 x SSC, 0.1 % SDS at 42° C ". There is no support in the specification for a hybridization conditions of 0.2 x SSC, 0.1 % SDS at 42° C. Applicant asserts on page 11 under part A. 'Status of the Claims' in lines 3-6 that support for the amendments can

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be found on pages 6-9, page 15 line 15; in the Examples on pages 23-24, and in the originally filed claims. However, no hybridization conditions are recited in the parts of the specification indicated or anywhere else in the specification, there is only a short recitation of wash conditions of 0.2 x SSC, 0.1 SDS at 42° C for 20 minutes and 3 times for 30 minutes at 65° C on page 15, line 15. Applicant is invited to point to the page and line number in the specification where support can be found. Absent of such support, Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 1-3, 6-10, 36 and 43-46 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/4/2004. Applicant's arguments filed 5/6/2004 have been considered but are not deemed persuasive.

Applicant asserts that the claimed subject matter is defined by structure and function to a discrete class of subject matter fully within the scope of the first paragraph of 112 (response page 13, lines 1-6). Contrary to Applicant's assertion the amended claims recite only hybridization language and that is not correlated with any function. See MPEP 2163 and the Revised Written Description Guidelines cited in the previous Office Action, which teach that a demonstration of correlation between a structure (i.e. a sequence) and a function (i.e. a specific activity) is required to adequately describe a broadly claimed genus.

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Claims 1-3, 6-10, 36 and 43-46 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method increasing disease resistance and of increasing native levels of at least one 4' *O*-methylated isoflavonoid compound in a leguminous plant that natively produces 4' *O*-methylated isoflavonoids by expressing an isoflavone *O*-methyltransferase gene of SEQ ID NO: 1, does not reasonably provide enablement for a method of increasing disease resistance and increasing levels of 4' *O*-methylated isoflavonoids in any plant that natively produces 4' *O*-methylated isoflavonoids by transformation using any isoflavone *O*-methyltransferase gene, or with a DNA fragment that hybridizes to SEQ ID NO: 1 under conditions of 0.2 x SSC, 0.1 % SDS at 42° C other than SEQ ID NO: 1; or for producing 4' *O*-methylated isoflavonoids by transformation of a non 4' *O*-methylated isoflavonoid producing plant using any isoflavone *O*-methyltransferase gene in combination with any number of DNA sequences encoding enzymes necessary for isoflavonoid biosynthesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/4/2004. Applicant's arguments filed 5/6/2004 have been considered but are not deemed persuasive.

Applicant asserts the amendments to the claims define the claimed subject matter to a discrete scope and the subject matter fully within the subject matter enabled by the working examples, the sequence listing and descriptions in the specification (response page 14, lines 1-3). The amendment to the claims does not correlate a function with the hybridization language. Since no function is attributed to the sequences that would hybridize to SEQ ID NO: 1 the scope

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is not discrete and is therefore not enabled, nor is it supported by the working examples or the descriptions in the specification as asserted by Applicant.

Given the unpredictability in the art as to which isolated polynucleotides would encode an isoflavone *O*-methyltransferase gene; the breadth of the claims encompassing methods of increasing disease resistance and of increasing levels of at least one 4' *O*-methylated isoflavonoid compound in a plant that natively produces 4' *O*-methylated isoflavonoids by expressing an isoflavone *O*-methyltransferase gene, or by expressing a DNA fragment that hybridizes to SEQ ID NO: 1 under conditions of 0.2 x SSC, 0.1 % SDS at 42° C; or by expressing a recombinant DNA sequence encoding a portion of an isoflavone *O*-methyltransferase gene; and a method of producing at least one 4' *O*-methylated isoflavonoid compound in a plant that does not produce 4' *O*-methylated isoflavonoid compounds by transformation with any isoflavone *O*-methyltransferase gene in combination with any number of the other necessary enzymes of isoflavonoid biosynthesis; the lack of guidance in the examples of the specification or in the prior art as to which non-exemplified DNA sequences would when transformed into a plant would either increase levels of, or produce 4' *O*-methylated isoflavonoids, one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictably eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified 4' *O*-methylated isoflavonoid biosynthetic enzymes and would require one of skill in the art to test in a myriad of non-exemplified plants for increased production or production of 4' *O*-methylated isoflavonoids in non-exemplified transformed plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

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No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
July 14, 2004



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